

REMARKS

Claims 1 through 7, 13, 14 and 16 are pending.

Claim 1 has been amended to reflect that the intermediate compound of formula (XIa) is salified within the inventive process for producing emtricitabine of formula (Ia). Support for this amendment can be found in the Application-as-filed.

Claim 1 has also been amended to reflect more conventional United States claim practice. Support for this amendments can be found in the Application-as-filed.

Claim 1 has been amended to reflect advantageous processes in which the salt of (XIa) is in an isolable solid form. Support for this amendment can be found in the Application-as-filed, for example in Claim 2.

Accordingly, Claim 2 has been canceled, as its subject matter has been incorporated into Claim 1.

Claim 13 has been amended to reflect that the intermediate compound of formula (XIId) is salified within the inventive process for producing the compound of formula (Ib). Support for this amendment can be found in the Application-as-filed.

Claim 13 has also been amended to reflect more conventional United States claim practice. Support for these amendments can be found in the Application-as-filed.

Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

Rejection under 35 USC 112

Claims 1 through 7, 13, 14, and 16 stand rejected as indefinite as the compound I(a) is not enabled for treatment with organic or mineral acid. Applicants respectfully submit that compound XI(a)(Claim 1) and XI(d)(Claim 13) are treated with an organic or mineral acid, rather than the compound I(a)(Claim 1) or I(b)(Claim 13), as emphasized in the claims as-amended. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claims 1 through 7, 13, 14 and 16 further stand rejected in Paragraph 1 of the outstanding Office Action over the recitation "salification."

Applicants respectfully submit that the claims are generally directed to inventive methods by which to form emtricitabine (Ia), which allows the compound to be readily separated out in its intermediate form. The separation of emtricitabine enantiomers has heretofore highly problematic.

Unexpectedly, Applicant's have found that an intermediate (XIa) used in the production of emtricitabine can readily be separated out as its salt, e.g. by reacting the intermediate (XIa) with an organic or inorganic acid to form a salt. In that regard, the Examiner's attention is kindly directed to the Application-as-filed on Page 9, lines 18 through 20, noting that acid is used to salify "the amino group of compound XIa."

Accordingly, Applicants respectfully submit that the recited "salification" of the compound of formula XI(a) by reaction with acid is enabled, as correctly alluded to by the Examiner in the outstanding Office Action at Page 3, Paragraph 2. Applicants more particularly respectfully submit that One Skilled in the Art would readily understand the claimed salification, especially when the claim is read in light of the specification. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claims 1 through 7, 13, 14 and 16 also apparently stand rejected over a lack of enablement for the transformation of the carboxylate group of (XIa) or (XIId) into an alcohol group in (Ia) and (Ib), respectively, as indicated in the outstanding Office Action on Page 4, Ref. Nos. 1, 4 and 6.

Applicants respectfully note the inventive salt-form of intermediate (XIa) is reduced, e.g. the menthol group removed, to produce the hydroxyl-containing compound emtricitabine (Ia). In that regard, the Examiner's attention is kindly directed to the Application-as-filed on Page 11, lines 15 through 22.

The present invention is primarily directed to the formation of a salt of intermediate compound (XIa) that allows ready separation of isomers during the production of emtricitabine. The subsequent reduction of intermediate compounds in the formation of emtricitabine is not considered a "critical and essential" feature of the claimed invention. Consequently, the recitation of a reduction step is not required. Nevertheless, the step of reducing compound XI(a) to yield emtricitabine (Ia) was recited in dependent Claim 10 as-filed. Solely to advance prosecution of the above-referenced case, Claim 10 was not elected. Should the Examiner deem it advisable, Applicants would be pleased to rejoin Claim 10 in the above-referenced application, however. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

Claim 2 stands rejected as a duplicate of Claim 1. Without addressing the merits of the rejection and solely to advance prosecution of the above-referenced case, the subject matter of Claim 2 has been incorporated into Claim 1 and Claim 2 has been canceled. Accordingly, Applicants respectfully request withdrawal of the foregoing rejection.

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CONCLUSION

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1 through 7 and 13, 14 and 16 are in condition for immediate allowance. It is requested that the Examiner telephone the undersigned if any questions remain to expedite examination of this application.

It is not believed that fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional fees are necessary to allow consideration of this paper, the fees are hereby authorized to be charged to Deposit Account No. 50-2193.

Respectfully submitted,

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